

**REMARKS**

Claim 1-45 are pending in the application. Claims 1-17, 19-38, and 42-45 are rejected. Claims 18 and 39-41 are withdrawn from consideration.

***Specification***

The abstract has been objected to because it exceeds 150 words in length and is not limited to a single paragraph. Applicant's amendments to the abstract are believed to overcome this objection.

***Claim Rejections - 35 U.S.C. § 112***

Claims 35, 36, and 42 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite.

With regard to claim 42, the Examiner is correct in that it should depend upon claim 39, which has been withdrawn from consideration. Applicant therefore withdraws claim 42 from consideration.

With regard to claims 35 and 36, Applicant respectfully submits that the claims are not indefinite. "Breadth of a claim is not to be equated with indefiniteness." M.P.E.P. § 2173.04 (citing *In re Miller*, 441 F.2d 689, 169 U.S.P.Q. 597 (CCPA 1971)). Although these claims do not recite specific geographical boundaries, it is clear that in claim 35 the user processors are located in the same geographical area in which the main processor and database are located, and in claim 36 the subsidiary processors and databases are located in geographical areas that are different from the one in which the main processor and database are located. Thus, claims 35 and 36 are sufficiently definite. Reconsideration and withdrawal of this rejection is respectfully requested.



patient data, and if the patient is eligible for the study, a study management center sends the doctor and initial suggested drug prescription. The doctor then has the option to confirm or adjust the prescription within the parameters of the clinical study protocol. The results are then sent to the host computer database for updating, and a hard copy of the drug prescription is printed.

Debusk also does not relate to the design of a clinical trial. Rather, Debusk relates to an information management system providing customized management of the use of medical resources (e.g., doctor time, equipment, and supplies) using user-configured software modules. Hospitals and health-care providers can buy an off-the-shelf software product that, through the use of the software modules, may be tailored to the facility's individual needs. This software may be run on any stand-alone or network personal computer.

Edelson does not make up for the deficiencies of Colon and Debusk. Edelson relates to a prescription creation system, which divides a single prescription into two components for fulfillment of one portion quickly and locally at higher cost, and another portion by remote mail order at a cost savings.

Umen relates to a document production system for preparing documents and managing the composition of textual information pertaining to studies of medical products. More specifically, a computer-implemented document production system manages the composition of textual information pertaining to studies of a medical product, stores drug information within a data storage and retrieval system, and organizes the information in order to generate drug documents according to predetermined document formats.

Thus, it is clear that none of the applied references, either alone or in combination, suggests the design of a clinical trial, as required by the claims. Thus each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to pass this application to issue.

Dated: September 8, 2003

Respectfully submitted,

By

*Laura C. Brutman*

Laura C. Brutman

Registration No.: 38,395

DARBY & DARBY P.C.

P.O. Box 5257

New York, New York 10150-5257

(212) 527-7700

(212) 753-6237 (Fax)

Attorneys/Agents For Applicant